Complete Summary

GUIDELINE TITLE

Nutrition practice guidelines for gestational diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Nutrition practice guidelines for gestational diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Sep. Various p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
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IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Gestational diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Evaluation
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Nutrition
Obstetrics and Gynecology

INTENDED USERS

Dietitians

GUIDELINE OBJECTIVE(S)

Overall Objective:

- To define medical nutrition therapy (MNT) shown to promote normoglycemia, provide optimum nutrition and reduce complications of gestational diabetes mellitus (GDM)

Specific Objectives:

- To define responsibilities within the scope of practice for registered dietitians that are carried out in collaboration with other health care providers
- To reduce variation in practice among registered dietitians
- To develop standards that can be tested for impact on clinical outcomes
- To define highest quality of care within cost constraints of the current health care environment
- To guide practice decisions that integrate medical, obstetrical, nutritional and behavioral elements
- To promote self-management education that empowers the patient to take responsibility for day-to-day management and provides the registered dietitian with data to make recommendations to adjust nutrition therapy, or recommend other therapies, to achieve clinical outcomes

TARGET POPULATION

Women at risk for or with documented gestational diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Screening/Risk Assessment

1. Risk assessment of gestational diabetes based on age, body weight, personal or family history of diabetes, ethnicity
2. Glucose challenge test (GCT) (screening test)
3. Oral glucose tolerance test (OGTT)

Initial Assessment

1. Medical and obstetrical history
2. Nutrition-focused assessment including height, weight, prepregnancy weight and body mass index (BMI), glucose challenge test, oral glucose tolerance test, hemoglobin A1c, hemoglobin/hematocrit (Hg/Hct)
3. Assessment of client´s understanding of diabetes and readiness to learn
4. Obtaining comprehensive diet history, including review of diet records and determination of meal and snack times, portion sizes and food preferences; evaluating current dietary intake; evaluation for current/potential gastrointestinal problems
5. Assessment of typical exercise/activity pattern; assessment of lifestyle factors.

Management/Medical Nutrition Therapy and Education

1. Providing meal plan
2. Providing self-management training (e.g., glucose self-monitoring, ketone testing, maintaining food records, meal planning, physical activity)
3. Determining need for insulin therapy
4. Reassessment and follow-up
5. Providing documentation to other relevant health care team members

MAJOR OUTCOMES CONSIDERED

- Blood glucose levels
- Maternal and fetal pregnancy outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The priorities for choosing articles to support the American Dietetics Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus were:

1. Randomized control trials to evaluate the effect of various factors (diet, exercise, self-blood glucose monitoring) on fasting and 1- and 2-hour blood glucose.
2. Cohort studies that evaluated various factors (diet, exercise, self-blood glucose monitoring) on the outcomes of pregnancy compared to desirable outcomes of all pregnancies (vaginal delivery of a normal term infant). Cohort studies were chosen that followed women during their pregnancy until delivery or followed offspring from birth to 4 or 5 years of age.
3. Case studies that compared cases (infants born of women who participated in regular physical activity throughout the pregnancy) with controls (infants born of women who did not have regular physical activity) or population-based descriptive studies, for example, the number of macrosomic infants born of women with different concentrations of fasting blood glucose measurements on the oral glucose tolerance test.
4. Consensus Statements from the American Diabetes Association or the American Dietetic Association that are based on the most recent research and practice guideline.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetics Association Health Services Research Task Force. This process is an adaptation of the US Preventive Task Force evidence analysis process.

Rating Scheme

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion (see the "Rating Scheme for the Strength of the Recommendations" field). Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Plus: indicates that the report clearly addresses issues of inclusion/exclusion, bias, generalization and data collection and analysis

Minus: indicates that the above issues are not adequately addressed

Neutral: indicates that the report is neither exceptionally strong nor exceptionally weak

NA: Indicates that report is not a primary reference and therefore the quality has not been assessed

Classes of Research Reports

A. Primary Reports of New Data Collection

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Decision analysis
- Cost-benefit analysis
- Cost-effectiveness study

Class R:

- Review article
- Consensus statement
- Consensus report

Class X:

- Medical Opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Ideal/Goal Values listed in the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus is based on a comprehensive review of published peer-reviewed research and literature. In addition, practice guidelines and recommendations supported by national consensus committees, were also used. In instances where guidelines and recommendations vary among consensus panels, the information was carefully analyzed.

Phase I in the development of the Nutrition Practice Guideline for Gestational Diabetes Mellitus includes the following steps:

Step One: Define the clinical question

Step Two: Conduct a comprehensive search of the literature

Step Three: Gather relevant articles and abstract key information

Step Four: Critique articles and rate the evidence

Step Five: Summarize and integrate results of the review

Step Six: Use the results

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetic Association Health Services Research Task Force in December 2000. This process is an adaptation of the United States Preventive Services Task Force evidence analysis process. ICSI process is designed as a practical approach that is user friendly for the clinician. ICSI classifies research reports as:

1. Primary reports of new data collection
2. Reports that synthesize or reflect upon collections of primary reports

Primary reports are categorized according to the level of evidence with category A (randomized, controlled trials) having the highest level of evidence or showing cause and effect. All other primary reports (cohort studies, case studies, nonrandomized trials with concurrent controls) are only able to show an association--not cause and effect. Reports that synthesize or reflect upon collections of primary reports are meta-analysis, systematic reviews, consensus reports, or medical opinion.

Studies and reports were evaluated individually and categorized according to the class of research report and the quality of the research (positive +, neutral, negative -).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A panel of experts, including practitioners and researchers with a depth of experience in the area of practice, convened as the American Dietetics Association (ADA) Medical Nutrition Therapy (MNT) Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus Writing Group. Their tasks were: first, to agree on a set of recommendations suitable for use in usual clinical situations based on scientific evidence, and where evidence is lacking, on extensive experience and expert opinion; and second, to write the guide (i.e., recommendation) for practice.

Studies and reports within a topic (for example, physical activity) were given a conclusion grade based on the available evidence. Grade I conclusion is supported by good evidence, Grade II by fair evidence, Grade III by limited evidence and Grade IV only by opinion. The Nutrition Practice Guideline for Gestational Diabetes Mellitus Evidence Analysis Workgroup reached a consensus on the conclusion grade for each topic.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion.

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The American Dietetic Association Medical Nutrition Therapy Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus has gone through a comprehensive peer-review process for technical accuracy and content and translation to practice, and meets the criteria for level III (gold level) validation as defined by the Quality Management Committee of the American Dietetic Association. At the gold level, recommendations are based primarily on a rigorous prospective effectiveness study. The effectiveness study for gestational diabetes mellitus was carefully designed to allow attribution of effects to the nutrition

activities that are being recommended in the practice guideline. The executive summary of the Gestational Diabetes Mellitus effectiveness study describes how design issues including: comparison groups, sample size, definition of key outcomes and other data collected (including patient/client characteristics, intervention/process factors, and outcomes) timing for data collection, data measurement and documentation procedures, and analysis were addressed for this study.

The Review Panel and Steering Committee included experts in the field (experienced dietetics practitioners, specialists, researchers, and educators) and experts and opinion leaders outside the dietetics profession including a nurse practitioner and physicians. The panel utilized a review form to focus feedback on important elements/criteria. In addition, the protocol was evaluated and reviewed for how reasonable expectations are for reimbursement, a critical element for securing medical nutrition therapy coverage in today´s health care market. Previous versions of this guideline have undergone technical accuracy and translation level I (bronze level) and level II (silver level), usability and acceptance validation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Conclusion grades (I-IV) are defined at the end of the "Major Recommendations" field.

Gestational Diabetes Mellitus MNT

Nutrtion therapy for gestational diabetes mellitus (GDM) is primarily a carbohydrate-controlled meal plan that promotes adequate nutrition with appropriate weight gain, normoglycemia, and the absence of ketonuria.

1. Number of medical nutrition therapy (MNT) visits

Setting: Ambulatory Care or adapted for other health care settings*.

Encounter	Length of contact	Times between encounters
1	60-90 minutes	1 week
2	30-45 minutes	1 week
3	15-45 minutes	1-3 weeks
4, 5, 6	15-30 minutes	2-3 weeks until delivery
Postpartum	15-30 minutes	At 6-12 weeks post-

		delivery, a review of glucose tolerance and postpartum nutrition plan is recommended.

* Face-to-face encounters are encouraged due to the preciseness and detail of data and recommendations that are discussed--weight changes, testing method and results, food type and amount, etc. Phone contact may be needed between encounters to collect additional data, assess therapy changes, and to provide information and support.

2. Clinical Assessment
    a. Laboratory Parameters

        Glucose goals:

        Blood Plasma
        (mg/dl)

        Fasting: ≤95 ≤105
        1-hr postprandial: ≤140 ≤155
        2-hr postprandial: ≤120 ≤130

        Hg: ≥11g/dl =<13.2 g/dl
        HbA1c: <6%
        Ketones: trace or absent
        Blood pressure: 120/80

    b. Nutrition/Physical
        - Weight gain goals are based on pre-pregnancy body mass index (BMI) (Grade I)
3. Therapeutic Lifestyle Changes

    Encounter in which behavioral topics are covered may vary according to client's readiness, skills, resources and need for lifestyle changes.

    a. Food and Meal Planning:
        - Calorie Level: ≥1800 kcal. Recommendations for a calorie level are best determined by monitoring weight gain, physical activity, appetite, and food, blood glucose and ketone records. (Grade I)
        - Hypocaloric Diets for Obese Women: At the current time caloric restriction must be viewed with caution. Restricting calories to 1200 kcal/day in obese women (BMI>30) with GDM results in ketonemia/ketonuria whereas restricting calories to ~1800 kcal/day does not result in ketonemia or ketonuria. (Grade I)
        - Carbohydrate: >40% kcal; 42% to 45% carbohydrate distributed among 6 to 8 meals and snacks throughout the day with smaller amounts of carbohydrate (15 to 45 g) at breakfast and snacks. (Grade III)

- Nonnutritive sweeteners: Generally safe in pregnancy. Moderation is advised.
- Protein: 0.8 gm/kg + 10 g. An additional 10 g per day in pregnancy, based on balance studies that show 1.3 to 2.1 g nitrogen (8.1 to 13 g protein) retention during pregnancy with the greater amount retained during the third trimester. (Grade I)
- Fat: <40% kcal; <10% saturated fat. During pregnancy, and in the treatment of GDM, the percentage of fat may be higher than generally recommended. 30-40% of total calories. Because GDM is a short-term condition, the total amount of fat is not designed for long-term chronic disease prevention.
- Sodium: Not routinely restricted.
- Fiber: May be increased for relief of constipation.
- Vitamins and minerals: Assess for specific individual needs. Iron at 12 weeks.
- Alcohol: Avoid
- Caffeine: Limit to <300 mg/day

b. Physical Activity
   - 30 minutes/day most days of the week. Regular physical activity decreases the common discomforts associated with pregnancy without a negative effect on maternal or neonatal outcomes. Regular physical activity is also beneficial in reducing insulin resistance, postprandial hyperglycemia and excessive weight gain. However, prolonged exercise(>60 minutes) is more likely to cause hypoglycemia in pregnancy. (Grade II)

c. Self-Monitoring of Blood Glucose
   - Self-monitoring of blood glucose provides valuable information to patients and dietitians on impact of food on blood glucose. Goals for blood glucose are fasting: $\leq$95 mg/dl, 1-hour: $\leq$140 mg/dl and 2-hour: $\leq$120 mg/dl. Mean serum glucose levels <86 mg/dl increase the risk for small for gestational age infants and mean glucose levels $\geq$105 mg/dl increase the risk for macrosomia. (Grade I)

Definitions:

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for medical nutrition therapy for gestational diabetes mellitus.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains conclusion statements that are supported by grading worksheets. These worksheets summarize the important studies pertaining to the conclusion. The quality of the evidence supporting key recommendations (i.e., calorie level, hypocaloric diets for obese women, weight gain, carbohydrate requirements, exercise and physical activity requirements, self-monitoring of glucose, insulin therapy, ketone testing, and postpartum care) is graded (positive, negative, neutral) for each study. The type of study is also identified.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- When blood glucose levels of women with gestational diabetes mellitus (GDM) are kept as near normal as possible, the outcome of the pregnancy is more successful.
- The field test results show that fewer women in the Nutrition Practice Guideline (NPG) group were treated with insulin (22.5%) compared with women in the usual care group (36.8%). Using less insulin therapy could mean lower healthcare costs and fewer follow-up encounters.
- Regular physical activity decreases the common discomforts associated with pregnancy without a negative effect on maternal or neonatal outcomes. Regular physical activity is also beneficial in reducing insulin resistance, postprandial hyperglycemia and excessive weight gain.
- Optimum neonatal outcomes occur in women who gain the recommended weight based on prepregnancy body mass index of the Institute of Medicine Guidelines. Overweight and obese women with gestational diabetes mellitus benefit from nutrition counseling by a dietician to decrease the rate of weight gain, fasting, and postpartum serum glucose, and normalize infant birthweight.
- Self-monitoring of blood glucose is an essential component of maintaining desirable blood glucose in women with gestational diabetes mellitus. Studies have shown the best outcomes when both fasting and 1- or 2-hour

postprandial blood glucose is monitored several times day and used to modify food intake or meal patterns and physical activity.
- Insulin therapy can prevent excessive maternal weight gain, macrosomia and fetal morbidity and mortality.
- The risks of developing type 2 diabetes mellitus can be reduced with lifestyle changes including healthy food choices and physical activity to promote weight loss.

Subgroups Most Likely to Benefit:

Women at highest risk for developing gestational diabetes, including:

- Women with marked obesity
- Women with a strong family history of type 2 diabetes or a personal history of gestational diabetes mellitus
- Certain ethnic groups with relatively high rates of carbohydrate intolerance (Hispanic, African American, Mexican, Native American, South or East Asian, Pacific Island or Indigenous Australian ancestry)

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These nutrition practice guidelines are meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This digital media publication is an integral part of the plans for getting the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus to all dietetics practitioners engaged in, teaching about, or researching gestational diabetes mellitus (GDM) as quickly as possible. National implementation workshops at various sites around the country and during the ADA Food & Nutrition Conference & Expo (FNCE) are also planned. Additionally there are recommended dissemination and adoption strategies for local use of the ADA MNT Evidence-Based Nutrition Practice Guideline for Gestational Diabetes Mellitus.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Nutrition practice guidelines for gestational diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Sep. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Sep

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

Nutrition Practice Guideline for Gestational Diabetes Mellitus Evidence Analysis Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Evidence Analysis Workgroup: Nanna A. Cross, PhD, RD (Consultant); Ellen Pritchett, RD, CPHQ (Facilitator); Deborah Thomas-Dobersen, MS, RD, CDE; Marion Franz, MS, RD, LD, CDE; Lea Ann Holzmeister, RD, CDE; Elvira Johnson, MS, RD, CDE; Diane Reader, RD, LD, CDE

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print and CD-ROM copies: Available from the American Dietetic Association, 120 South Riverside Plaza, Suite 2000, Chicago, IL 60606-6995; Phone: (800) 877-1600, ext. 5000; Web site: www.eatright.org; E-mail: sales@eatright.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2003. The information was verified by the guideline developer on August 6, 2003.

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